

## **REMARKS**

### ***Overview***

In the Office Action under reply, claims 1-33 are pending. Applicants acknowledge with appreciation the Examiner's withdrawal of the rejection under 35 U.S.C. §103(a) from the previous Office Action. The pending claims have been rejected as follows:

(1-2) in two separate rejections, claims 1-33 stand rejected under 35 U.S.C. §112, second paragraph, as indefinite;

(3) claims 1-33 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement; and

(4) claims 1-33 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

These rejections are addressed in part by the amendments made herein, and are otherwise traversed for the reasons set forth below.

### ***Claim Amendments***

By the amendments made herein, claims 1 and 19 have been amended to clarify the claim language. No new matter has been added by these amendments.

### ***First rejection under 35 U.S.C. §112, second paragraph***

Claims 1-33 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner states that the second compound is not clearly defined in the claim. Applicants traverse this rejection.

Applicants have amended claims 1 and 19 for the sole purpose of clarifying the claim language. The claims have been amended to specify that the second compound comprises both: (1) at least one crown ether group; and (2) a moiety selected from acidic groups, transition metal binding groups and diazo groups. Applicants respectfully request withdrawal of the rejection.

***Second rejection under 35 U.S.C. §112, second paragraph***

Claims 1-33 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner states that amine-containing compounds, crown ethers, acidic groups, transition metal binding groups and diazo groups are all indefinite. Applicants traverse this rejection.

Regarding “amine-containing compounds,” the Examiner provides no explanation or justification for declaring this term indefinite. In fact, the self-describing term is not indefinite: an amine-containing compound is any chemical compound that contains an amine group. One of ordinary skill in the art would instantly be able to determine whether a given compound is an amine-containing compound simply by checking for the presence of an amine group (e.g.,  $\text{-NH}_2$ ,  $\text{-NHR}$ , etc.). Furthermore, the term “amine group” is well known in the art; a definition can be found in any general textbook of organic chemistry. For example, amines are defined in the textbook Organic Chemistry, 6<sup>th</sup> edition, by T.W.G. Solomons (1996, Wiley, New York, New York, page 70). Additional guidance is provided by the specification, for example, in paragraph [0033]. For these reasons, one of ordinary skill in the art would immediately be able to determine whether a given compound contains an amine moiety.

Regarding “crown ethers,” again, the Examiner provides no explanation or justification for declaring this term indefinite. This term is also well known in the art, and is also defined in most basic textbooks of organic chemistry. Furthermore, the specification provides guidance. For example, in paragraphs [0021] and [0022], crown ethers are defined (“those cyclic ethers having four or more oxygen atoms”). For these reasons, one of ordinary skill in the art would immediately be able to determine whether a given compound contains a crown ether group.

Regarding “acidic groups,” the Examiner states that “it cannot be determined how acidic the acidic groups are,” and continues by stating that there is “no indication as to how the level of acidity is measured.” Claim 1 states that the second compound comprises “a moiety selected from acidic groups.” The claim specifies, therefore, only that the group is acidic. It is well known that a wide variety of groups are considered acidic. Acidic groups include, for example, carboxylic acid groups, and, more generally, groups that are capable either of donating a proton or accepting an electron pair. Based on, for example, the chemical structure of a group in question, one of ordinary skill would be able to determine whether or not the group is acidic. While the

Examiner expresses concern about “how acidic the acidic groups are” and “level of acidity,” whether a group is acidic or not is a separate question from how strongly acidic the group happens to be. The determination of whether a compound falls within the scope of the claims, which is the concern of indefiniteness, does not require a determination of whether an acidic group is more or less strongly acidic. One of ordinary skill in the art would in general be able to determine whether a group is acidic without having to measure the strength of acidity of the group.

Regarding “transition metal binding groups,” again, the Examiner provides no explanation or justification for declaring this term indefinite. Guidance for this type of group is provided, for example, in paragraphs [0025] and [0026] of the specification. Furthermore, the concept of groups that bind transition metals is well known in the art. From sequestering agents to ligands, a plethora of organic and inorganic textbooks and journals are devoted to the topic of transition metal binding groups. Thus, a wide variety of known groups, as well as analogues of such groups, can be identified as transition metal binding groups based on the commonly available literature. In addition, simple tests are available to determine whether a new group is a transition metal binding. These tests are well documented and are commonly available to those of skill in the art. In general, therefore, one of ordinary skill would be able to determine, given the disclosure of the application and commonly available references, whether a given group is a transition metal binding group.

Regarding “diazo groups,” again, the Examiner provides no explanation or justification for declaring this term indefinite. The specification (e.g., paragraph [0029]) provides a definition of the diazo group ( $=N_2$ ), and one of ordinary skill would immediately be able to determine whether a given compound contains such a group.

***First rejection under 35 U.S.C. §112, first paragraph***

Claims 1-33 stand rejected under 35 U.S.C. §112, first paragraph, because the specification is not enabling. This rejection is traversed.

The Examiner acknowledges that the specification is enabling for using benzoic acid, the transition metal binding groups listed in paragraph [0026] of the specification, diazo groups, and compounds 1-5. The Examiner asserts, however, that the specification “does not reasonably

provide enablement for using all eight radicals listed in claim 4.” The Examiner has failed to satisfy the requirements for such a rejection.

First, MPEP §2164.04, citing *In re Marzocchi*, 439 F.2d at 224, 169 USPQ at 370, states that “it is incumbent upon the Patent Office, whenever a rejection on [the basis of enablement] is made, to explain *why* it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement.” The Examiner provides no basis for his assertion of non-enablement, except to say that “[t]here is insufficient disclosure of starting materials that would place such a diverse genus of compounds in possession of the public.” By this the Examiner must be suggesting that one of ordinary skill would not know “where to start” in order to prepare the materials of the claims. Although some experimentation would be necessary in order to prepare many of the compounds encompassed by the claims, the amount of experimentation that would be “undue” must be determined in view of the Wands factors (*In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). These factors, which are described in MPEP §2164.01(a), lead to the conclusion that undue experimentation would not be required for one of ordinary skill in the art to practice the claimed invention. For example, synthetic chemistry, wherein a target molecule is prepared in a step-by-step fashion beginning with commonly available starting materials, is a highly developed field, and the level of one of ordinary skill is high. There is a great deal of predictability for the basic synthetic reactions that are used by synthetic chemists in order to convert starting materials into more desirable products, such as the compounds of the pending claims. The specification provides one of skill in the art with the direction that is necessary to envision any of the compounds that are encompassed by the claims. Once such a compound is envisioned, the skilled practitioner is left with the task of devising a synthetic pathway to prepare the compound. Such a task would not require “undue” experimentation, because of the large amount of supporting literature and commonly available knowledge in the field of synthetic chemistry.

Second, and as stated in MPEP §2164.01(b), “[a] key issue that can arise when determining whether the specification is enabling is whether the starting materials or apparatus necessary to make the invention are available.” Even a cursory look at commercial suppliers of organic chemicals reveals that a very wide variety of acids, crown ethers, diazo compounds, and transition metal binding groups (such as each of the eight radicals listed in claim 4) are available.

Third, it is not necessary (nor is it desired) for applicants to describe the synthesis of each and every compound that is encompassed by the claims. Enablement need only bear a reasonable relationship to the scope of the claim. See, e.g., *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052 (Fed. Cir. 2005) (“The scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.”) (quoting *In re Fisher*, 427 F.2d 833 (CCPA 1970)).

The Examiner also states that “[i]n addition, there is no reasonable assurance that such an alleged genus of compounds would possess all of the alleged properties for use.” It is not clear what the Examiner is referring to as “alleged properties for use.” Citing *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993), MPEP §2164.04 provides that the “examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure.” The Examiner simply states that there is no assurance that the claimed compounds would “possess all the alleged properties for use.” Such a statement does not substitute for providing a “reasonable explanation” as to why enablement is inadequate. Without the reasonable explanation that is required by *In re Wright*, applicants are not able to address any specific concerns that the Examiner may have with regard to enablement in relation to “the alleged properties for use.” While some experimentation may be required to determine the specific properties of the compounds encompassed by the claims, “[e]nablement is not precluded by the necessity for some experimentation such as routine screening.” *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988).

For at least these reasons, the disclosure fully enables the claims, and applicants accordingly request withdrawal of the rejection.

***Second rejection under 35 U.S.C. §112, first paragraph***

Claims 1-33 stand rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. This rejection is traversed.

The Examiner appears to be rejecting the claims because the phrases “amine containing compounds,” “crown ether group,” “acidic groups,” “transition metal binding groups,” and “diazo groups” do not adequately describe the invention. As the following discussion will make clear, these terms are indeed sufficient to adequately describe the invention such that one of

ordinary skill in the art would agree that applicants had possession of the invention at the time the application was made.

First, according to MPEP §2163 I.A., “[t]here is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. In re Wertheim, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976).” The Examiner states that the terms in question are not art-recognized terms, but provides no evidence or arguments to support this position. A search of nearly any textbook on organic chemistry shows, however, that these terms are indeed art-recognized.

Second, the Examiner, citing *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 at 1406, states that “[a] written description of an invention involving a chemical genus... requires a precise definition, such as by structure, formula, [or] chemical name of the claimed subject matter sufficient to distinguish it from other materials,” and further states that “[a]pplicants’ functional definitions in the claimed formula simply lack the precision required by the Court of Appeals for the Federal Circuit.” However, the terms “amine-containing compounds,” “crown ethers,” and “diazo groups” are clearly terms that refer to structural characteristics. For example, and as discussed hereinabove, amine-containing compounds are compounds that contain an amine group. Similarly, crown ether groups and diazo groups are well-defined, art-recognized terms that leave no room for speculation as to the structural identity of the group.

With regard to the remaining two terms, “acidic groups” and “transition metal binding groups,” these terms may be considered functional definitions, but they also describe chemical properties of the groups. MPEP §2163 II.3.ii states that “[t]he written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice... or by disclosure of *relevant, identifying characteristics*, i.e., structure or other physical and/or *chemical properties*, by *functional characteristics* coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics...” (emphasis added). Therefore, it is clearly appropriate to identify chemical groups by their chemical properties. For example, the term “acidic group” describes the function of the group (e.g., to donate a proton), or it may describe the chemical property of the group (e.g., acidic). Again, as discussed hereinabove, these terms clearly identify

chemical moieties that are art-recognized, characterized, tabularized, and generally well-documented.

In any case, even if the terms of the claims were considered functional definitions, MPEP 2173.05(g), citing *In re Swinehart*, 439 F.2d 210, 169 USPQ 226 (CCPA 1971), states that “[t]here is nothing inherently wrong with defining some part of an invention in functional terms. Functional language does not, in and of itself, render a claim improper.”


Third, it must be noted that, according to MPEP §2163 I., “[c]ompliance with the written description requirement is a question of fact which must be resolved on a case-by-case basis. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116 (Fed. Cir. 1991).” Thus, while a chemical or functional definition is not appropriate in some cases, the terms used in the pending claims refer to well-defined chemical groups that would be understood by anyone of ordinary skill in the art.

It is therefore evident that the terms used in the claims are adequately supported and described by the specification, and that the written description requirement has been met. Accordingly, applicants respectfully request withdrawal of the rejection.

**CONCLUSION**

Applicants submit that the claims of the application are in condition for allowance. Applicants respectfully request withdrawal of the rejections, and prompt issuance of a notice of allowance. If the Examiner has any questions concerning this communication, or would like to discuss the application, the art, or other pertinent matters, a telephone call to the undersigned would be welcomed.

Respectfully submitted,

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